TCT-772

Emergency Aortic Balloon Valvuloplasty in Era of Transcatheter Aortic Valve Replacement: Results from Two Centers Experience

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Background: Balloon aortic valvuloplasty (BAV) has often a compassionate rule in the treatment of symptomatic and severe aortic stenosis (AS). Aim of this work was to evaluate the clinical outcomes of BAV performed in emergency clinical setting.
Methods: Between September 2007 and September 2012, forty-two consecutive emergency BAV were performed because of severe AS symptomatic for refractory pulmonary edema (71%) or cardiogenic shock (29%).
Results: Most of the patients were female (60%) with mean age of 86±5 years and Logistic Euroscore I of 40±21%. Baseline echocardiographic data showed an aortic valve area of 0.5±1.4 cm2 and a mean transvalvular gradient of 46±14 mmHg, high pulmonary hypertension (50±15 mmHg) and left ventricular ejection fraction of 41±14%. Coronary artery disease was present in 52%, with multivessel disease in 24% of the cases. During BAV, a coronary revascularization was performed in 26% of the pts. An undersized balloon (20 mm) was used in 71% of cases. Drop of 33±20 mmHg of peak aortic gradient was observed after BAV and in 57% of the procedures one balloon inflation was enough. In-hospital death rate was 28%. All-cause death at 6 months was 45%. Transcatheter aortic valve replacement (TAVR) was performed in 56% of survival pts with a significant improvement in clinical outcomes (NYHA class II and no mortality at 6 months follow up in all pts).
Conclusions: Although high mortality rate was observed after BAV in emergency clinical setting (refractory pulmonary edema or cardiogenic shock due to severe AS) survival pts had a chance to be able to complete the treatment of AS by TAVR procedure.

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The Prognostic Significance of Changes in B-type Naturetic Peptide (BNP) after Transcatheter Aortic Valve Replacement (TAVR): THE PARTNER I EXPERIENCE

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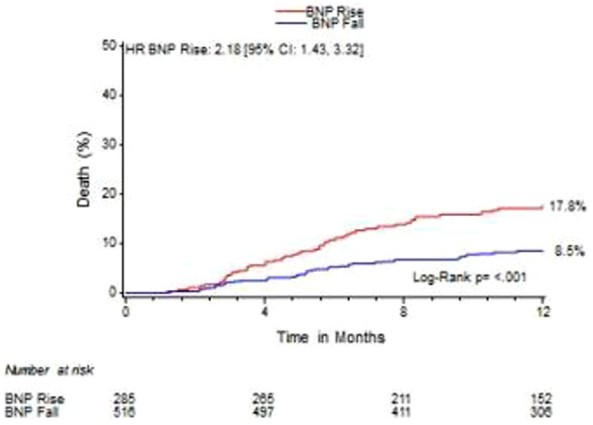
Background: BNP is synthesized in cardiac ventricular tissue in response to increased wall stress and is known to be elevated in patients with aortic stenosis, especially those with clinical heart failure. We sought to characterize the timing and prognostic significance of changes in BNP levels after TAVR in the PARTNER I trial.
Methods: A total of 801 patients treated with transfemoral (TF) TAVR had BNP levels determined at baseline, 1w, 6 m, 12 m, and 24 m after therapy. We further divided patients into Group I (those with rising BNP levels at 1m) and Group II (those with stable or falling BNP).
Results: Median Baseline BNP [IQR] was 619 [293, 1438], falling to 610 [289, 1342] at 1w and 479 [238, 1006] at 1m. Thereafter, BNP levels remained stable at 6m (357 [175, 827]), 1y (341 [176, 729]), and 2y (346 [187, 782]). Mortality was increased at 6m, 1y, and 2y for patients with rising BNP (See figure). Similarly, repeat hospitalization was higher at 6m (18 vs 10%, p=0.0008), 1y (24 vs 13%, p=0.0002), and 2y (40 vs 31%, p=0.006). Patients in Group I were more likely to have moderate/severe AR post-procedure (14.7 vs 9.3%, p=0.03596). Moderate or severe mitral regurgitation was similar between Group I and Group II at 1m echo (24 vs 18%, respectively, p=0.08), but was more common in Group I patients on the 6m echo (25 vs 16%, p=0.02).
Conclusions: BNP levels are elevated and tend to fall rapidly after TF-TAVR. Rising BNP levels after TAVR are associated with a significantly increased risk of death or rehospitalization and post-procedure moderate/severe AR.



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Circulatory Support is Associated with Higher Mortality During TAVR

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Background: Circulatory support (CS) may be needed during TAVR, but little is known about the incidence, outcomes, and predictors of its use.
Methods: The study population included all patients in the PARTNER trial and Continued Access Registry (CAR) that underwent TAVR. Patients that received CS (intra-aortic balloon pump [IABP] or cardiopulmonary bypass [CPB]), either elective pre-procedure or urgent intra-procedure, were compared to patients that did not receive CS.
Results: Of the 2538 patients, 203 (8%) received support, including CPB (n=133, 66%) or IABP (n=70, 34%). Compared to those not receiving support, patients receiving CS were more likely male (64% vs 51%, p< 0.0001), undergo transapical access (81% vs 39%, p<0.0001), have prior CABG (60% vs 41%, p < 0.0001), lower left ventricular EF (47 vs 53%, p<0.001), and moderate or severe mitral regurgitation (28% vs 21%, p = 0.03). The incidence of CS was higher in the CAR than in the PARTNER trial (9% vs 5%), partly due to an increased proportion of transapical cases (50% vs 20%, respectively). The use of circulatory support was associated with greater procedural complications, including major vascular complications (17% vs 5%, p< 0.0001) and valve embolization (5% vs 0.5%, p<0.0001). CS was associated with a significantly higher 30 day all-cause mortality (25% vs 5%, p< 0.0001), and was higher in patients that received CPB compared to IABP (32% vs 13%, p=0.003). The mortality difference between the CS and non-CS groups persisted at two years (48% vs 28%, p< 0.0001). The specific indication for CS, elective pre-procedure or urgent resulting from a complication, will be separately analyzed to determine the effect on outcome.
Conclusions: The use of CS during TAVR is surprisingly frequent, associated with procedural complications, and portends a higher early and late mortality. CS was used more frequently in registry patients as compared to randomized trial patients. Identifying patients most likely to benefit from CS may represent an opportunity to improve outcomes.

TCT-775

Cost-Effectiveness Of Transcatheter Aortic Valve Replacement By Minimalist Or Standard Approaches

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Background: Transcatheter aortic valve replacement (TAVR) can be performed via different access routes and settings. The economic benefits of TAVR over SAVR in a variety of procedural settings are unclear. Our goal was to compare cost of TAVR by

transfemoral (TF) route in the catheterization laboratory (C-TF) or hybrid room (OR-TF) and OR non-TF TAVR.
Methods: A retrospective study was performed on 174 patients who underwent TAVR at a single US academic institution using the SAPIEN valve from 11/2011 to 4/2013. Patients were stratified into 3 groups: C-TF TAVR (n=51), OR-TF TAVR (n=39), and OR-non-TF TAVR (n=84). All C-TF patients were performed with i.v. sedation and TTE. The OR-TF and OR-non-TF patients were performed in the hybrid OR with general anesthesia and TEE. Total variable cost, hospital payment, and contribution margin were utilized to determine the financial viability of TAVR.
Results: Compared to OR-TF and OR-non-TF, C-TF had a significantly lower procedure time ($p<0.001$) and postop ventilator hours ($p<0.001$). Resource utilization in terms of ICU ($p<0.001$), postop ($p<0.001$), and total hospital LOS ($p<0.001$) was significantly higher in OR-non-TF patients. Total variable cost in the OR-non-TF TAVR was the highest ($57,197±23,142), but hospital payment was comparably the highest ($62,647±58,826); leading to the highest contribution margin ($19,594±43,553). Total variable cost and hospital payment were lowest in the C-TF group, leading to a contribution margin of $15,529±19,556 (Table).

Table. Admission Resource Use and Costs

	C-TF(n=51)	OR-TF(n=39)	OR-non-TF(n=84)	p value
OR time, min	160 ± 85	229 ± 70	234 ± 49	<0.001
Ventilator hours	1.7 ± 10.1	23.4 ± 66.7	48.4 ± 131.0	<0.001
ICU LOS, hrs	21.9 ± 17.7	50.5 ± 64.1	98.3 ± 138.2	<0.001
Post-op LOS, days	3.7 ± 2.7	4.7 ± 3.2	9.1 ± 7.5	<0.001
Total hospital LOS	6.0 ± 4.9	7.1 ± 5.7	11.2 ± 8.5	<0.001
Total variable cost	$45,173 ± 16,988	$52,268 ± 16,480	$57,197 ± 23,142	<0.001
Hospital payment	$45,412 ± 28,158	$59,931 ± 20,954	$62,647 ± 58,826	0.002
Contribution margin	$15,529 ± 19,556	$10,421 ± 20,389	$19,594 ± 43,553	0.27

All values are mean±SD; all cost data is in $US.

Conclusions: This is the first study comparing the economic impact of the minimalist and standard approaches to TAVR. The economic benefits of TAVR in all groups were shown to be financially viable (positive contribution margin). Resource utilization was the least in the C-TF group, but hospital reimbursement was also the lowest. A more defined reimbursement strategy for these high-risk patients is required.

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Safety of Axillary and TransAortic Approaches for Transcatheter Aortic Valve Replacement in patients older than 85 years old: Results from Italian CoreValve Registry

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Background: Trans-femoral (TF) approach represents the first choice of vascular access for transcatheter aortic valve replacement (TAVR). When not feasible, alternative approaches such as axillary artery (TA) or, more recently, direct ascending aorta (DA) are used for self-expandable valve implantation. Aim of this work was to evaluate the safety of TAVR with self-expandable valve through these alternative vascular approaches in ≥ 85 years old patients (pts).
Methods: From the Clinical Service® (former Italian CoreValve Registry) dataset, 1317 consecutive pts underwent TAVR with 3° generation CoreValve in 7 Italian sites between June 2007 and November 2012, were included in this analysis. Pts were divided into two groups according to the vascular access: TF or alternative approaches (TA and DA). Primary end point was the 30-day safety evaluation according to VARC-2 criteria.
Results: Four hundred and eighty-four pts (37%) had an age ≥ 85 years (range, 85-99). TF access was used in 81% and alternative approaches in 19% of cases (16% TA and 2.5% DA). Sex female was higher in TF (64% vs 50%, respectively, p=0.014) while the Logistic Euroscore I was higher in the second group (21% vs 26%, respectively, p=0.039), as well as the presence of coronary artery disease (41% vs 58%, p=0.004) and history of myocardial infarction (14% vs 23%, respectively, p=0.036). There was non significant difference regarding to devices success between two approaches (95% vs 96%, respectively, p=0.8). Combined early safety end point was similar between two groups (28% vs 22%, respectively, p=0.23), as well as the individual components, except for a significant higher incidence of acute kidney injury (stage II- III) in TF compared to alternative accesses (30% vs 17%, respectively, p=0.010). All-cause of death and cardiovascular death at 30 days and 1 year of follow up were similar into two groups irrespective of different type of vascular access.
Conclusions: When TF approach was not feasible because of anatomical reasons, the alternative approach such as axillary artery (TA) or, more recently, direct ascending aorta (DA) could lead to a self-expandable valve implantation safely also in elderly patients.

TCT-777

Long-term Clinical Outcomes in Nonagenarian Patients Undergoing Transcatheter Aortic Valve Implantation: Multicenter Brazilian Registry

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Background: Transcatheter aortic valve implantation (TAVI) has been established as a standard treatment in inoperable and high-risk elderly pts with severe aortic stenosis. However, there is no data thus far assessing the safety and the efficacy of TAVI in pts older than 90 years. We therefore sought to evaluate the early- and long-term clinical outcomes in nonagenarian pts undergoing TAVI.
Methods: Between January 2008 and February 2013, pts with symptomatic severe aortic stenosis underwent and were enrolled in the Brazilian multicenter registry. Among a total of 418 pts, 370 were < 90 years and 48 (13%) were nonagenarian.
Results: Nonagenarian pts were 12 years older than pts < 90 years (92.4 years vs. 80.12 years; p<0.001). Compared with pts < 90 years, nonagenarian pts had higher STS risk score (19.44±13.84% vs. 14.03±12.38%; p=0.005), lower body mass index (24.55±3.40 vs. 26.31±4.61 kg/m2; p=0.01), but higher baseline left ventricular ejection fraction (61.74±12.32% vs. 57.27%±15.60%, p=0.03). 30-day and 1-year main clinical outcomes are presented in Table.

	30 days			1 year *		
	< 90 years	≥ 90 years		< 90 years	≥ 90 years	
	no of pacients (%)		p-value	no patients (%)		p-value
All cause-death	8.4%	10.4%	0.59	18.9	18.8%	0.87
Cardiovascular death	7%	6.2%	0.99	12.4%	10.4%	0.64
Stroke	3.8%	4.2%	0.70	5.4%	8.3%	0.52
Death/ stroke	8.6%	8.3%	0.99	21.9%	27.1%	0.46
Major bleeding	16.5%	10.4%	0.28	17.6%	10.4%	0.21
Safety endpoint**	21.6%	20.8%	0.90	-	-	-

All clinical events were adjudicated according to VARC-2 criteria.
* Kaplan-Meier estimates .
** Composite of death, stroke, major bleeding, renal insufficiency, major vascular complication, re-intervention or repeat surgery.

Conclusions: In this real world Brazilian registry, nonagenarian pts who underwent TAVI had favorable and similar early- and long-term clinical outcomes as compared with pts < 90 years. The treatment of symptomatic severe aortic stenosis in nonagenarians pts with TAVI deemed to be a non-futility approach.